

APPENDIX D TO SUBPART A OF PART 26—
CRITERIA FOR ASSESSING EQUIVA-
LENCE FOR POST- AND
PREAPPROVAL

I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:

- A. Appropriate statutory mandate and jurisdiction.
- B. Ability to issue and update binding requirements on GMP's and guidance documents.
- C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
- D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
- E. Substantive current good manufacturing requirements.
- F. Accountability of the regulatory authority.
- G. Inventory of current products and manufacturers.
- H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

- A. Standards of education/qualification and training.
- B. Effective quality assurance systems measures to ensure adequate job performance.
- C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of inspections:

- A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
- B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
- C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective use of surveillance systems:

- A. Sampling and analysis.
- B. Recall monitoring.
- C. Product defect reporting system.
- D. Routine surveillance inspections.
- E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for preapproval inspections:

- A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
- B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
- C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
- D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
- E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
- F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

APPENDIX E TO SUBPART A OF PART 26—
ELEMENTS TO BE CONSIDERED IN DE-
VELOPING A TWO-WAY ALERT SYS-
TEM

1. Documentation

- Definition of a crisis/emergency and under what circumstances an alert is required
- Standard Operating Procedures (SOP's)
- Mechanism of health hazards evaluation and classification
- Language of communication and transmission of information

2. Crisis Management System

- Crisis analysis and communication mechanisms
- Establishment of contact points
- Reporting mechanisms

3. Enforcement Procedures

- Followup mechanisms
- Corrective action procedures